Avoca®
A WCG Company

Sponsor SOP Package

For the Management of GCP-Compliant Clinical Trials

In need of regulatory compliant procedures for the management of clinical trials within your Sponsor organization?

WCG now offers Sponsors a regulatory compliant and operationally lean suite of Standard Operating Procedures (SOPs) curated for Sponsors utilizing a highly outsourced operational model. With this suite, Sponsors will receive 26 individual procedural documents including 2 policy-level documents and 24 SOP-level documents to use as-is or to customize to meet their organization's specific needs. These documents have been developed by a multidisciplinary bench of industry experts, while leveraging insights gained through WCG Avoca's Quality Consortium and consulting expertise. All documents provided comply with applicable federal regulation and harmonized guidances, including US Code of Federal Regulation, EU Regulation and Directives, and ICH Guidelines.

PROCEDURAL DOCUMENTS COVER CONTENT IN RELATION TO THE FOLLOWING:

General Policy Includes antibribery/anticorruption, privacy, and confidentiality.	**General Procedures** Includes procedural development, personnel management, contractual agreements, etc.
Clinical Development Includes trial document development, safety management, blinding procedures, etc.	**Clincal Operations** Includes site management and monitoring, deviations, trial supply management, etc.
Quality Assurance Includes inspection preparation, audit management, management of issues and misconduct, qualification of service providers, etc.	**Data Management** Includes data management processes for study start-up, ongoing maintenance, and study close-out activities.
Regulatory Affairs Includes regulatory submissions, reporting requirements and registries, etc.	**Project Management** Includes transfer of regulatory obligations, project planning and communication, study oversight, TMF, and risk management.

For more information, visit www.theavocagroup.com

wcg™